

KY Hepatitis Connections

On behalf of the KY Adult Viral Hepatitis Program, we wish you and your loved ones a blessed and wonderful Christmas season! We are pleased to share with you the December issue of KY Hepatitis Connections. The KY Hepatitis Connections provides current information, opportunities for viral Hepatitis continuing professional education and information about educational materials available.

Please feel free to forward and/or copy and distribute to other professionals in your network. Your knowledge and input are greatly valued, as we are committed to keeping you up to date on shared progress in the medical community on viral Hepatitis and its impact on our families throughout the Commonwealth. Join us on Facebook, KY Viral Hepatitis.

Kathy Sanders, RN MSN



64th Annual meeting of the American Association for the Study of Liver Diseases

Recently the American Association for the Study of Liver Diseases met for their annual meeting in Washington, DC on November 1-5, 2013. Click on the link below to review the Conference Reports and all current detailed data and reporting.

Read More: http://www.natap.org/2013/AASLD/AASLD.htm

Costs for Hepatitis C Treatment Skyrocket

WASHINGTON, DC — The expense of telaprevir-based triple therapy for hepatitis C — including adverse event management — is \$189,000 per sustained viral response, report investigators. "Our findings indicate that the benefit-cost ratio is lower than projected, based on results of the registration trials," lead investigator Andrea Branch, MD, from the Icahn School of Medicine at Mount Sinai in New York City.

Kian Bichoupan, MBS, who is Dr. Branch's first-year PhD clinical research student, presented the results at The Liver Meeting 2013. The number seemed to alarm session comoderator Sammy Saab, MD, from the David Geffen School of Medicine at UCLA, who called it "very surprising." It is "at least double what we think the cost is. I didn't know the cost of actually curing someone was so high," he said.

Read More: http://hepatitiscnewdrugs.blogspot.com/2013/11/costs-for-hepatitis-c-treatment.html

AASLD 2013: Successful Hepatitis C Treatment Reduces Risk of Liver Cancer and Death, But Most Remain Untreated

Hepatitis C treatment that leads to viral suppression significantly reduces the likelihood of liver disease progression and liver-related mortality, but most patients remain untreated, according to a presentation at the 64th AASLD Liver Meeting last week in Washington, DC. Other studies found that a growing proportion of liver transplants are due to hepatocellular carcinoma, which can still occur even after treatment.

Over years or decades, chronic hepatitis C virus (HCV) infection can lead to serious liver disease including cirrhosis, hepatocellular carcinoma (HCC), and end-stage liver failure. Up to 20% of people with chronic hepatitis C develop cirrhosis within 20 years, and among these the risk of HCC may reach 4%. Successful treatment of hepatitis C has the potential to slow or halt liver disease progression and reduce the risk of long-term consequences including liver cancer and liver-related death.

Jeffrey McCombs from the University of Southern California in Los Angeles looked at the impact of HCV viral load suppression with treatment on the risk of morbidity and mortality among chronic hepatitis C patients receiving care through the U.S. Veterans Health Administration.



Hepatitis C Drug Sofosbuvir Still Effective at 24 Weeks

SAN DIEGO, California — New data from 4 phase 3 trials with the hepatitis C (HCV) drug sofosbuvir (SOF) and ribavirin (RBV) show that a 12-week regimen is effective in treating HCV genotypes 1 through 6. Twenty-four-week sustained virologic response (SVR) is essentially identical to 12-week SVR, bolstering confidence that the drug combination represents a cure. Those with genotype 3 infections are better served with a 16-week course of treatment.

The new work extends the results of the studies out to 24 weeks after treatment cessation. Twenty-four weeks was the traditional milestone for HCV treatments, but in recent years, the US Food and Drug Administration and industry have gravitated toward the 12-week time point. However, with new drugs set to greatly affect HCV treatment, it is important to consider this older benchmark, according to Kris Kowdley, MD, director of the Liver Center of Excellence at the Digestive Disease Institute at the Virginia Mason Medical Center in Seattle, Washington, who presented the research here at the American College of Gastroenterology (ACG) 2013 Annual Scientific Meeting and Postgraduate Course.

Read More: http://www.medscape.com/viewarticle/813352?src=emailthis



Is the genotype 3 of the hepatitis C virus the new villain?

Source

Division of Gastroenterology and Hepatology, Geneva University Hospital, Geneva, Switzerland.

Abstract

The genotype 3 of the hepatitis C virus (HCV) has been long considered an easy-to-treat infection, with higher cure rates ($^{\sim}70\%$) than other viral genotypes with the standard combination of pegylated interferon- α and ribavirin. However, the relative insensitivity of this genotype to most protease inhibitors and the recent unexpected data on decreased effectiveness of sofosbuvir, have raised questions on how to achieve universal cure, a goal that seems reasonable for other genotypes. In addition, increasing clinical and experimental data show that HCV genotype 3 may be associated not only with severe steatosis, but also with accelerated fibrosis progression rate and increased oncogenesis. Conclusion: Currently available data suggest that we should increase our efforts to understand the virology and pathogenesis of HCV genotype 3, aiming at better and more potent, genotype-targeted treatments. (Hepatology 2013;).



Vertex Focuses Investment on Future Opportunities in Cystic Fibrosis and Other Key Research and Development Programs and Reduces Workforce Related to INCIVEK

Changes result from the continued and rapid decline in the number of people being treated with INCIVEK as new hepatitis C medicines near approval-

-370 positions, including 175 in Massachusetts, to be eliminated, primarily related to support of INCIVEK-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- <u>Vertex Pharmaceuticals Incorporated</u> (Nasdaq: VRTX) announced the company will focus its investment on future opportunities in cystic fibrosis and other high-potential research and development programs and is reducing its workforce related to the support of INCIVEK following the continued and rapid decline in the number of people being treated with INCIVEK as other new medicines for hepatitis C near approval. The company is eliminating 370 positions, primarily related to the support of INCIVEK, representing approximately a 15 percent reduction in the company's global workforce. Approximately 175 positions are being eliminated in Massachusetts. The company anticipates a \$150 million to \$200 million reduction in 2014 operating expenses compared to 2013.

"We have a tremendous opportunity to further transform the treatment of cystic fibrosis and advance our other promising research and development programs," commented Jeffrey Leiden, M.D., Ph.D., Chairman, President and Chief Executive Officer of Vertex.

"As new medicines for hepatitis C near approval, fewer people are starting treatment with INCIVEK, and as a result, we are reducing our workforce supporting this medicine. Today is a difficult day for everyone at Vertex, but these changes are necessary as we work to develop new breakthrough medicines in the coming years," concluded Dr. Leiden.

Following the changes, Vertex expects to have approximately 1,800 employees worldwide, including approximately 1,300 in Massachusetts. All employees affected by the restructuring are being offered outplacement services as well as a comprehensive severance package based on their length of employment with Vertex.

The company provided additional financial information, including updated financial guidance for 2013and a financial outlook for 2014, as part of its third quarter financial results announced today in a separate press release. Read More: http://investors.vrtx.com/releasedetail.cfm?ReleaseID=80114





Hepatitis C: Faldaprevir regimen is effective as first treatment for genotype 1

SAN DIEGO – A regimen containing the oral investigational protease inhibitor faldaprevir is efficacious and safe as initial treatment for chronic hepatitis C virus genotype 1, a randomized phase III trial showed. A team led by Dr. Christophe Moreno, a gastroenterologist at the Erasme Hospital, Université Libre de Bruxelles, Brussels, conducted the trial, known as STARTverso 1, among 652 patients in Europe and Japan.

More than three-fourths of patients given a faldaprevir-containing interferon-based regimen had achieved a sustained virologic response at 12 weeks after the end of treatment (SVR12), Dr. Moreno reported. This compared with only about half of patients given a placebo-containing regimen.

A low dose of faldaprevir worked just as well as a high one. In addition, most faldaprevir-treated patients met criteria for early treatment success and were therefore able to stop treatment after half the full duration.

Read More: http://hepatitiscnewdrugs.blogspot.com/2013/10/hepatitis-c-faldaprevir-regimen-is.html?spref=fb

JAMA study questions FDA's shorter drug approval times

(Reuters) - New drugs that receive expedited review by the Food and Drug Administration are being tested on fewer patients, leaving many safety questions unanswered even after they are approved, a study released on Monday in the Journal of the American Medical Association found.

Study authors Thomas Moore of the Institute for Safe Medication Practices and Dr Curt Furberg, a professor at Wake Forest School of Medicine, examined the development times, clinical testing and risks associated with 20 new drugs approved in 2008. Eight were given expedited review and 12 standard review.

It found that expedited drugs underwent a median of 5.1 years of clinical testing before being approved, compared with 7.5 years for those that underwent a standard review. But in many cases safety monitoring trials that were supposed to be conducted after the products were approved were either not conducted, not completed, or not submitted to the FDA. Read More:

http://in.reuters.com/article/2013/10/28/us-usa-fda-jama-idINBRE99R12920131028





Seronegative hepatitis C virus infection in patients with lymphoproliferative disorders

J Viral Hepat. 2013 Oct 20. doi: 10.1111/jvh.12181. [Epub ahead of print]

Department of Hematology, Institute of Hematology and Blood Transfusion, Warsaw, Poland. **Abstract**

It has been reported that hepatitis C virus (HCV) RNA may be present in serum and/or lymphoid cells in the absence of specific circulating antibodies.

Methods:

The current study analysed seronegative HCV infection in patients with lymphoproliferative disorders. We studied 77 anti-HCV-negative patients (45 male and 32 female, mean age 54.8 ± 14.2 years) with various lymphoproliferative disorders.

Results:

HCV-RNA was detected by RT-PCR in plasma, peripheral blood mononuclear cells (PBMC) and bone marrow. Furthermore, the presence of viral nonstructural protein 3 (NS3) was determined in PBMC and bone marrow by immunostaining. HCV-RNA was detectable in at least one compartment in 27 (35.1%) patients. Viral RNA was found in bone marrow in 22 patients (28.6%), in PBMC in 13 (16.9%) and in plasma in 10 (13%) patients. In nine patients, evidence of infection was confined to the bone marrow compartment. Viral load in HCV-RNA-positive plasma ranged from 15 to 1.17 × 103 IU/mL. NS3 was detected in all but two HCV-RNA-positive bone marrow samples and in all but one HCV-RNA-positive PBMC samples. All 27 HCV-RNA-positive patients remained anti-HCV-negative when tested again after 6-12 months, but only four remained HCV-RNA positive.

Conclusion:

In conclusion, among patients with lymphoproliferative disorders, HCV can be present in plasma, PBMC and bone marrow despite the lack of circulating specific antibodies. Further studies are required to analyse the phenomenon of seronegative infection and to determine whether such patients are infectious.

Center Watch: Hepatitis Clinical Research Trials

Hepatitis Clinical Research Trail Listings in Immunology Hepatology Infections and Infectious Disease vaccines:

Below is a listing of Hepatitis Medical Research Trials actively recruiting patient volunteers. Click on the link below to find more detailed information on research studies being done in Kentucky.

Read More: http://www.centerwatch.com/clinical-trials/listings/ctrc/condition/79/hepatitis/?mp=hepfi



Hepatitis C Screening and Evaluation: Clinical Decision Tool

Publication of the Clinical Decision Tool (CDT) for Hepatitis C Screening and Evaluation marks a milestone for the American Gastroenterological Association (AGA). This CDT is the first in a series of care pathways created for the "Clinical Service Lines" (CSL) component of AGA's "Roadmap to the Future of GI" initiative. The Roadmap to the Future of GI is designed to provide gastroenterologists with a single source for clinical tools needed to practice within the emerging value-based reimbursement environment. These tools have been created using a process steeped in the scientific rigor characteristic of AGA publications, combined with immediate access and the applicability needed for clinical practice.

The Roadmap to the Future of GI was originally presented to the AGA Governing Board during its strategy retreat in July 2011. It was first described in a July 2012 article in *Clinical Gastroenterology and Hepatology*¹ and subsequent sections of the AGA website (www.gastro.org). The AGA initially committed to fully develop 3 CSL including (a) Hepatitis C Screening and Evaluation; (b) Colorectal Cancer Prevention; and (c) Inflammatory Bowel Disease. Beginning components of these 3 CSL can be referenced within the Practice Section of the AGA website.

Read More: http://www.gastrojournal.org/article/S0016-5085(13)01286-9/fulltext

Estrogen protects women with NASH from severe liver fibrosis

New research suggests that estrogen protects women with nonalcoholic steatohepatitis (NASH) from severe liver fibrosis. According to the study published online in *Hepatology*, a journal of the American Association for the Study of Liver Diseases, men are at higher risk of more severe fibrosis compared to women prior to menopause, but liver fibrosis severity is similar in men and post-menopausal women.

Non-alcoholic fatty liver disease (NAFLD) includes a range of liver disorders from simple fatty liver to inflammation, fibrosis, and cirrhosis. With the rapid rise in obesity, diabetes and metabolic syndrome, the prevalence of NAFLD—the result of insulin resistance—has also steadily increased. In fact, studies suggest that the NAFLD prevalence is 10% to 30%, making it the most common liver disease in the U.S.

Read More: http://hepatitiscnewdrugs.blogspot.com/2013/10/estrogen-protects-women-with-nash-from.html





Expert Guidance on Timing of Treatment for HCV

Source: Treat Now or Later in HCV? Expert Guidance for Individual Scenarios

Use this Interactive Decision Support Tool to enter your patient's specific characteristics and then see what Ira M. Jacobson, MD; Paul Y. Kwo, MD; Andrew J. Muir, MD, MHS; Mark S. Sulkowski, MD; and Norah Terrault, MD, MPH, choose as their management approach.

With just a few clicks through pull-down menus, this Interactive Decision Support Tool will allow you to enter data, including patient characteristics and treatment history. Once those data are provided, the tool will present insight from 5 HCV experts regarding whether they would treat now or defer therapy for that particular patient—and if they would defer, what specific type of future regimen would they be waiting for.

The recommendations are depicted in a graphical view, showing the choices of all 5 experts. In addition to educating on expert management strategies and their rationale, the tool also provides an opportunity to record whether the experts' recommendations influence your own decision making. Look for the "Next" tab on the Expert Insight results page to provide this feedback.

Read More:

http://www.clinicaloptions.com/Hepatitis/Treatment%20Updates/HCV%20Timing/Interactive%20Tool/hcv.aspx

Physicians not following CDC guides on HCV screening

SAN DIEGO — Despite new guidelines issued by the CDC in 2012 calling for hepatitis C screening for everyone born between 1945 and 1965 regardless of other risk factors, only a small fraction of that population is being screened, a speaker said here.

"Screening for HCV in this population is very important," Ritu Gupta, DO, of Oakwood Hospital and Medical Center in Dearborn, Mich., said during the American College of Gastroenterology Annual Scientific Meeting.

Researchers retrospectively reviewed charts at two outpatient primary care clinics of 1,578 patients born between 1945 and 1965 to determine whether they had been screened for HCV and the method of screening, anti-HCV antibody or HCV RNA testing.

Of the patients — 569 men and 1,009 women; mean age 56 years — only 31 (2%) were screened for HCV, the study found. The mean age of the 21 men and 10 women who were screened was 57 years. One patient (3%) was screened via HCV RNA testing, while the remainder were screened via anti-HCV antibody testing.

Read More: http://www.healio.com/infectious-disease/hepatitis-resource-center-2013/physicians-not-following-cdc-guides-on-hcv-screening



Newly Approved Ultrasound Device Eliminates Risks and Pain of Liver Biopsy

DETROIT, Oct. 29, 2013 /PRNewswire/ -- Henry Ford Hospital is the first in Michigan to use a pioneering ultrasound device that can help patients with liver disease avoid invasive biopsies to manage their disorders.

FibroScan[®] replaces repeated and sometimes painful liver biopsies for patients with chronic hepatitis C and B, fatty liver diseases and other hepatic disorders with a quick and painless procedure similar to the familiar ultrasound tests used to track pregnancy and diagnose internal diseases.

The device is based on a technology called transient elastography, which measures liver "stiffness" to assess disease and guide ongoing treatment.

"FibroScan® is designed to measure liver fibrosis using a painless, non-invasive method of assessing many of the same conditions measured with biopsy," says Stuart Gordon, M.D., Director of Hepatology at Henry Ford Hospital. "It's an outpatient procedure taking less than 15 minutes."

Read More: http://www.prnewswire.com/news-releases/newly-approved-ultrasound-device-eliminates-risks-and-pain-of-liver-biopsy-229729261.html

Hepatitis C: Special Risks for Women

Hepatitis C is preventable and curable but, an expert tells us, it still poses special risks for women and children.

Knowing whether we have a hepatitis C viral infection is especially important for us women, because we can unintentionally pass this dangerous virus on to loved ones or a newborn child.

Certain lifestyle or life history events put women at greater risk for contracting hepatitis C infection. In my case, because I worked in a research lab studying hepatitis C for several years, I received an annual test to screen for the virus in my blood. Fortunately, my tests were always negative.

To put women's hepatitis C risks in perspective, we reached out to an expert.

"Women born after 1976 have a very low risk of hepatitis C infection, less than approximately 5 out of 1000 women," explained Camila S. Graham, MD, MPH, of the Division of Infectious Disease at Beth Israel Deaconess Medical Center in Boston, an expert in hepatitis C and the special risks faced by women and children. "About 60 percent of new cases of hepatitis C are from injection drug use, and about 20 percent are from sexual transmission," Dr. Graham added.

Read More: http://www.everydayhealth.com/hepatitis/hepatitis-c-special-risks-for-women-2683.aspx



Pregnant women with hepatitis C may pass heartier viral strain to newborns, study suggests

Infants who get hepatitis C from their mothers during childbirth may inherit a viral strain that replicates more quickly than strains found in non-pregnant hosts, according to a new study published Oct. 27 in *Nature Medicine*. The findings, from a team in The Research Institute at Nationwide Children's Hospital, are the first to describe how a virus that has infected 180 million people worldwide takes advantage of immune changes during pregnancy.

About 1 percent of all pregnant women worldwide have hepatitis C, caused by a highly adaptable virus known as HCV that infects liver cells. In 3 to 5 percent of these pregnancies, the virus is passed to the newborns, accounting for the majority of new childhood HCV infections. Between 15 and 45 percent of people infected with HCV are able to mount an immune response sufficient to eradicate the virus. But in most cases, the virus eludes immunity, leading to a chronic infection that increases the risk of liver failure or liver cancer.

More Than Half of Hepatitis C Patients can't withstand current therapies or waiting for new treatments

DETROIT – More than half of chronic hepatitis C patients studied in a new research project led by Henry Ford Hospital were not treated for the potentially fatal disease, either because they couldn't withstand current therapies or because they, or their doctors, were waiting for new treatments.

In a second, related study, Henry Ford researchers found that while the disease is not yet curable, there is a significant "lost opportunity" for hepatitis C patients to achieve the current best result of treatment.

Both studies are being presented at the annual meeting of the American Association for the Study of Liver Diseases being held in Washington, DC, Nov. 1-5.

Stuart C. Gordon, M.D., director of the Hepatology section at Henry Ford, and lead author of the first study, said it was launched because of a lack of information about the subject.

Read More: http://hepatitiscnewdrugs.blogspot.com/2013/11/more-than-half-of-hepatitis-c-patients.html





Medicare considers coverage of hepatitis C screening

Medicare officials will spend the next several months deciding whether to cover screening for hepatitis C, after other public health agencies recommended one-time screening for baby boomers.

The agency is scheduled to issue a formal proposal for possible screening coverage in March 2014 and make a final decision in June 2014.

In a memo issued Sept. 5, officials at the Centers for Medicare and Medicaid Services (CMS) asked the public for input. Agency officials are specifically interested in clinical studies and other evidence showing that screening leads to an improvement in either short- or long-term outcomes.

Initial public comments from physicians and other health care providers were supportive of coverage. The commenters wrote that they favored screening because the condition is often asymptomatic and because there are effective treatments available.

Earlier this year, the United States Preventive Services Task Force (USPSTF) recommended that physicians offer one-time screening for hepatitis C virus (HCV) to baby boomers born between 1945 and 1965. The task force pointed to recent data showing that about three-fourths of HCV patients in the United States were born between 1945 and 1965.

Read More: http://www.gihepnews.com/news/top-news/single-article/medicare-considers-coverage-of-hepatitis-c-screening/660ffbdfa47aa8fffb765589fbfc6886.html

Hepatitis C Vaccine Phase I Clinical Trial Kicks Off in Korea

BLUE BELL, Pa., Oct. 21, 2013 /PRNewswire/ — Inovio Pharmaceuticals, Inc. (NYSE MKT: INO) announced that the safety, tolerability and immunogenicity of its therapeutic vaccine for hepatitis C (INO-8000/VGX-6150) will be studied in a phase I clinical trial in chronically HCV infected patients. Under a 2011 collaborative development agreement, Inovio's affiliate, VGX International Inc. (KSE: 011000), is fully funding and conducting the study at multiple sites in Korea. Inovio is also planning to evaluate this hepatitis C (HCV) vaccine in additional clinical studies in the U.S. beginning in 2014. Dr. J. Joseph Kim, Inovio's President and CEO, said, "More effective antiviral drugs have changed the prognosis for patients with hepatitis C; however, treatment failures remain and combination with an immunotherapeutic approach could make the difference for many patients. In preclinical studies, Inovio's HCV immunotherapy has shown to generate powerful T cell responses in the liver, which could be important in clearing HCV-infected liver cells. We have already shown in published clinical studies that our vaccines generate best-in-class T-cell responses. In this study, the effects of Inovio's HCV immunotherapy will be directly tested in patients who have previously failed standard drug therapies. We look forward to entering the hepatitis C treatment arena, which is one of the fastest-developing markets in healthcare, with a projected value of \$20 billion by the end of the decade."

Read More: http://www.hepatitiscentral.com/mt/archives/2013/10/hepatitis-c-vaccine-phase-i-clinical-trial-kicks-off-in-korea.html?eml=hepcen197



The Flu and Hepatitis C: High Risk of Complications

Experts weigh in on how to overcome fear of the flu shot, and why it is especially important for people with hepatitis C to get vaccinated.

Fall and winter months mean flu season is coming, and with it the many possible complications that come with influenza. People with chronic diseases like hepatitis C need to protect themselves from the flu because they are at higher risks for flu-related complications.

In the United States, more than 3 million people are infected with hepatitis C, though most who are don't know it. If you are one of these people, you are at risk of flu complications including worsening of your underlying liver condition, pneumonia, bronchitis, sinus infections and ear infections.

Depending on the year, from 3,000 to 49,000 people die from flu-related complications annually. In fact, according to the U.S. Centers for Disease Control (CDC), each year more than 200,000 in the United States are hospitalized due to influenza.

But you can lower your risk of being hospitalized for flu complications by getting the flu shot. A recent Japanese study showed that the flu vaccine can be protective against hospitalization for people with hep C. Vaccination for influenza cut the odds of being hospitalized in half for a group of 408 patients who had chronic hepatitis C, as reported in the medical journal *Liver International* in August 2013.

Read More: http://www.everydayhealth.com/hepatitis/flu-and-hepatitis-c-high-risk-complications-4636.aspx

Hepatitis C Online Course

Hepatitis C Online Course is a self-study, interactive course for medical providers on Hepatitis C infection. Features include a color coded master bibliography, embedded video, and clinical calculators. The project is brought to you by the University of Washington in collaboration with the International Antiviral Society-USA (IAS-USA). Free CME credit and free CNE credit are available. Funded by the Centers for Disease Control and Prevention.

- Module 1: Screening and Diagnosis of Hepatitis C Infection
- Module 2: Evaluation, Staging, and Monitoring of Chronic Hepatitis C
- Module 3: <u>Management of Cirrhosis-Related Complications</u>
- Module 4: Evaluation and Preparation for Hepatitis C Treatment



Veterans Affairs Research Supports CDC Recommendation to Screen Baby Boomers for Hepatitis C

WASHINGTON, Nov. 2, 2013 /PRNewswire/ -- In 2012, the Centers for Disease Control and Prevention (CDC) recommended a one-time screening for all Americans born between 1945 and 1965. It is estimated that 1 in 30 baby boomers has been infected with hepatitis C virus (HCV) and most don't know it. HCV is a serious liver disease including liver cancer, which is the fastest-rising cause of cancer-related deaths and the leading cause of liver transplants in the US.

Researchers at the Department of Veterans Affairs (VA) studied the health records of 5,500,392 veterans. Of those, 64.2 percent of baby boomers and 54.7 percent overall -- or more than 2.9 million -- had at least one VA screening for HCV. Of those screened, 9.9 percent of the baby boomers had HCV infection, compared with 1.7 percent of those born before 1945 and 1.1 percent of those born after 1965.

After extrapolating the infection data to the veterans not yet screened, researchers concluded that up to 51,000 more veterans of the baby boomer generation could be identified with HCV. The VA has been a leader in adopting new care models such as telehealth and Specialty Care Access Network-Extension for Community Healthcare Outcomes (SCAN ECHO) in order to expand the VA capacity to take care of any additional veterans identified as having HCV infection through expanded screening. SCAN ECHO is a collaboration between Dr. Sanjeev Arora, the Director of Project ECHO at the University of New Mexico, and the VA. The SCAN ECHO project links VA primary care providers in local VA community outpatient clinics with specialist teams at VA academic medical centers to help manage patients who have conditions requiring complex care. The SCAN ECHO model enables primary care providers to share best practices and obtain case-based learning. Through SCAN ECHO, VA primary care clinicians gain new competencies to provide care that was not previously available in their communities.

Read More: http://www.prnewswire.com/news-releases/veterans-affairs-research-supports-cdc-recommendation-to-screen-baby-boomers-for-hepatitis-c-230333091.html

High prevalence of HCV found in baby boomers via ED screening

WASHINGTON — About 12% of baby boomers who went to the emergency department for another reason then agreed to screening for hepatitis C were found to exhibit positive HCV reactivity, James W. Galbraith, MD, of the department of emergency medicine at the University of Alabama at Birmingham said in discussing a late-breaking abstract at The Liver Meeting.

These preliminary results in a high-risk population that was previously unaware of HCV infection highlights the ED as an important place to screen for HCV, he said.

Read More: http://www.healio.com/infectious-disease/hepatitis-resource-center-2013/high-prevalence-of-hcv-found-in-baby-boomers-via-ed-screening



The standard practice of watchful waiting in regards to treatment has been widespread among many patients and medical providers. This abstract nicely sums up the dangers of this approach:

Evaluation of the Long-Term Health Outcomes Associated with Earlier Versus Later Initiation of Treatment in Previously Untreated Patients with Chronic Hepatitis C Virus Genotype 1 Infection

BACKGROUND & AIM:

To address the ongoing debate on the downstream costs and sequelae associated with waiting to treat chronically infected hepatitis C virus (HCV) patients, a decision-analytic Markov model assessed the long-term health outcomes associated with treating patients in the non-cirrhotic stage and in the cirrhotic stage.

METHODS:

The analysis modeled two cohorts of treatment-naïve chronic HCV genotype 1 patients with a mean age of 52 from a US third-party payer perspective for a lifetime horizon: one cohort initiating treatment in the non-cirrhotic stage, and the other starting treatment in the cirrhotic stage.

The model included the following regimens:

- sofosbuvir (SOF) in combination with pegylated interferon plus ribavirin (PR) for 12 weeks,
- telaprevir (TLV) plus PR for 24-48 weeks,
- boceprevir (BOC) plus PR for 28-48 weeks, and PR for 48 weeks.

Sustained virologic response (SVR) and adverse event rates were based on published data (SVR = 92% vs. 80% for sofosbuvir plus PEG/RBV,82% vs. 66% for telaprevir plus PEG/RBV, 64% vs. 55% for boceprevir plus PEG/RBV and 58% vs. 33% for PEG/RBV in patients without and with cirrhosis, respectively).

Transition probability, utility, and cost estimates (in 2013 US dollars) were based on a literature review, public sources, and consensus by a panel of 4 hepatologists.

RESULTS:

Cases of liver disease complications were more than *triple* in the cohort of patients with cirrhosis than in the cohort without cirrhosis. Among the 4 regimens, sofosbuvir plus PEG/RBV had the most favorable health outcomes.

CONCLUSIONS:

This study projects that the watchful waiting approach to the treatment of HCV genotype 1 could lead to substantially more cases of advanced liver disease. Earlier treatment with more effective therapies like sofosbuvir could curb future liver disease and the downstream costs associated with advancing disease.



Hepatitis C Antibody with Reflex to Hepatitis C Virus RNA, Quantitative, Real-Time PCR

Laboratory Support of Diagnosis and Management

Clinical Background

Viral hepatitis is a relatively common disease (1% to 2% of the United States population) caused by a diverse group of hepatotropic agents that lead to liver inflammation and cell death. Five hepatitis viruses have been well characterized (A, B, C, D, and E; Table 1). Table 1 is provided for informational purposes only and is not intended as medical advice. A physician's test selection and interpretation, diagnosis, and patient management decisions should be based on his/her education, clinical expertise, and assessment of the patient.

Hepatitis A and E viruses (HAV, HEV) are transmitted through the fecal-oral route and manifest as acute or asymptomatic disease. There is no chronic carrier state and serious sequelae are rare, although both HAV and HEV can cause acute fulminant liver failure and HEV can cause fulminant disease in pregnant women. Hepatitis B, C, and D viruses (HBV, HCV, HDV) may establish persistent infections with significant morbidity and mortality. All 3 are transmitted parenterally. HBV and HCV are also transmitted through sexual contact and perinatally. HDV is unique in that it is a "defective" virus that can replicate only in the presence of HBV. HDV coinfection (HDV and HBV) significantly increases the severity of disease. Acute HCV infection may be asymptomatic, but most infections are chronic; chronic infection with HBV or HCV may lead to cirrhosis and hepatocellular carcinoma.

In the United States, viral hepatitis is generally caused by HAV, HBV, or HCV. Other causative viruses include cytomegalovirus (CMV), Epstein-Barr virus (EBV), and human immunodeficiency virus (HIV). Hepatitis may also be due to other diseases or medications.

A variety of immunologic and molecular assays are available for diagnosing viral hepatitis and monitoring treatment response. This guide provides an overview of available tests and indications for their use.

Read More:

http://www.questdiagnostics.com/testcenter/testguide.action?dc=CF ViralHepatitis&tabview=true



AASLD - Interferon-Free HCV Tx Benefits Mentally Ill

WASHINGTON -- Hepatitis C (HCV) patients with mental comorbidities, such as depression or bipolar disorder, can be successfully treated with an interferon-free drug regimen, a phase II trial showed.

Action Points

- Note that this study was published as an abstract and presented at a conference. These data and conclusions should be considered to be preliminary until published in a peer-reviewed journal.
- Note that this uncontrolled trial demonstrated similar rates of virologic response among patients with and without psychiatric comorbidities treated with sofosbuvir and ribavirin.
- Be aware that patients who participate in clinical trials may be more adherent than the general population.

The combination of ribavirin and the investigational agent sofosbuvir was equally effective in patients with and without significant mental health disorders, according to Amy Nelson, RN, of the National Institute of Allergy and Infectious Diseases in Bethesda, Md.

Importantly, both groups of patients were equally likely to adhere to the medication and to appear for study visits, she told MedPage Today at the annual meeting of the American Association for the Study of Liver Diseases.

Read More: http://hepatitiscnewdrugs.blogspot.com/2013/11/aasld-interferon-free-hcv-tx-benefits.html?spref=fb

ECHO model cost-effective for HCV

WASHINGTON – Using the ECHO model of primary care to treat hepatitis C is cost saving in 35% of patients and very cost effective overall, according to a retrospective analysis presented by Dr. John B. Wong, at the annual meeting of the American Association for the Study of Liver Diseases.

Project ECHO (Extension for Community Healthcare Outcomes) was begun at the University of New Mexico, Albuquerque, and has been adopted by the Veterans Affairs department, among other organizations, as a means of extending primary care to those who might not otherwise have access.

This is not about the antiviral treatment, it's about the engagement of primary care physicians, to train them, educate them, and help them take care of patients with hepatitis C," said Dr. Wong, chief of the division of clinical decision making at Tufts Medical Center, Boston. "It's about increasing access," he added.

Dr. Wong presented the results of a cost-effectiveness analysis he and his Tufts colleagues conducted on a study of ECHO's effectiveness in treating HCV, published in the New England Journal of Medicine in 2011 (N. Engl. J. Med. 2011;364:2199-207).



Wishing you a Wonderful Christmas Holiday



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